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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, ON THE DATE INDICATED BELOW.

BY: _____ Date: Jan 15 2004

MAIL STOP NON-FEE AMENDMENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Patent Application of Stanley Stewart Davis, *et al.*	:	Group Art Unit 1615
Conf. No.:	6578	:	
Appln. No.	09/841,228	:	Examiner: Sharon Howard
Filed:	April 24, 2001	:	
For:	NASAL DRUG DELIVERY COMPOSITION	:	Attorney Docket No. **10774-57US (WESR/P21724US)**

REQUEST FOR NEW, NON-FINAL OFFICE ACTION

The applicants have received an Office Action in the above identified patent application, mailed January 2, 2004 (Paper No. 19) ("the Office Action"). It is a non-final Office Action.

The applicants hereby request issuance of a new, non-final Office Action (with the period for response re-started). Paper No. 19 fails to address any of the substantive points raised by the applicants in their Request for Reconsideration, filed October 30, 2003, ("Previous Response") and is deficient in that the Examiner has not explained why she believes the applicants' arguments presented in the Previous Response to be unpersuasive. As such, the Office Action fails to facilitate the progress of this application and is in violation of 37 C.F.R. § 1.104 and M.P.E.P. 707.

In the Office Action, the Examiner rejected the claims under 35 U.S.C. § 102(b) as being anticipated by the Ducharme reference and, under 35 U.S.C. § 103(a) as being unpatentable over the Ducharme reference in combination with the Collins reference and the Ducharme reference individually. In response, the applicants prepared and the Prior Response in which they:

(i) pointed out to the Examiner that Ducharme is not a prior art reference under 35 U.S.C. § 102, subpart (b) and,

(ii) distinguished Ducharme and the Ducharme-Collins combination on several technical and legal bases, despite the Examiner's legal error.

Subsequently, the applicants received the Office Action in which the Examiner merely changed the subpart of § 102 under which Ducharme is applied as prior art. The reasons for the rejections provided in Paper No. 19 are identical and an apparent *verbatim* repetition of to those presented in the prior Office Action, mailed August 11, 2003, and do not take into account any of the points addressed by applicants differentiating Ducharme and Collins-Ducharme from the claimed invention. The Examiner does not explain why she does not accept the applicants' argument that (i) the oils disclosed in Ducharme are not the same as the claimed oils and, (ii) none of the references discloses a composition wherein 50 weight percent of the drug included in the composition is dissolved in the oil phase alone. Instead, the Examiner has merely used the Office Action to correct her initial legal error of applying Ducharme under § 102(b), an error which the applicants did not use to avoid addressing the substantive merits of the reference. At best this omission is careless and non-productive; at worst, applicants could interpret it to mean that the Examiner has not reviewed their Prior Response.

Accordingly, the Office Action is non-responsive, non-productive, and fails to facilitate progress of the prosecution of this application before the United States Patent Office. A response to this Office Action would necessarily present the same subject matter as the response that was filed previously. Applicants' submission of such response would be repetitive, redundant, and wasteful of both this Office's resources and the resources of the applicants.

The applicants respectfully request that the Examiner issue a new, non-final Office Action including the proper statutory grounds of rejection upon which each of the prior art references is applied, and containing a substantive well-reasoned rationale as to why the applicants' points of technical differentiation between the claimed invention and the prior art references are not persuasive, should such rejections be maintained.

In the alternative, as the applicants firmly believe that the claims are allowable based upon the arguments set forth in their Request for Reconsideration, filed October 30, 2003, reconsideration and allowance of the claims at the earliest opportunity is requested.

Respectfully submitted,

STANLEY STEWART DAVIS, *et al.*

15 January 2004 By: Kristyne A. Bullock
(Date)

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